EXHIBIT B

INTRODUCTION

Clinutren® 1.5 Fibre, the composition of which is attached hereto as Exhibit D, has been designed to fulfill the nutritional requirements of elderly population at risk of malnutrition but also takes into account the correction of the intestinal ecology through its content of fiber (2.5 g /100ml).

Since the content of fiber is relatively high and may result in undesired abdominal symptomatology a tolerance study was conducted. The aim of the study was to have a similar tolerance of the fiber supplemented product compared to Clinutren® 1.5, the composition of which is attached hereto as Exhibit C, that is known to be well tolerated. In addition the examination of the composition of the fecal microbiota, biochemical markers of inflammation at the intestinal and systemic levels were also evaluated.

METHODS

Subjects and study design

89 elderly volunteers (70 women and 19 men) were enrolled to participate in a prospective double blind placebo controlled and randomized study with two groups in parallel. Volunteers were recruited in ten nursing homes of the Barcelona region. Participants were at risk of malnutrition as assessed by the MNA (score between 17 and 23.5). The primary outcome in this non-inferiority trial is the questionnaire on gut comfort and wellbeing (GCWB) that all participants had to be able to answer. The questionnaire is based on 8 questions (symptoms) that can be answered within 5 levels of increasing severities from 0 to 4 (0 meaning no symptoms and 4 severe clinical manifestations). An average of the 8 different items was then calculated. The participants have answered the questionnaire at the beginning of the study, 2, 4 and 6 weeks after, for a total of four times during the study.

Treatments

The volunteers were allocated to two treatment groups in equal numbers after randomization and stratification for gender and antibiotherapy in the previous three months. Clinutren® 1.5 and Clinutren® 1.5 Fibre were used as oral supplements. They were given in 200 ml cups twice a day targeting a daily intake equal to 400 ml and 600 Kcal during 5 weeks with

an additional week at the beginning of the study with progressive intake until reaching the desired quantity.

Anthropometrics measurements

Body weight was recorded at baseline and 6 weeks after the initiation of the product intake. The MNA score (including the MNA short form) was performed prior to inclusion in the study.

Biochemical analysis

Albumin, pre-albumin, (1-glycoprotein, C reactive protein (CRP) individually and combined in the Prognostic Inflammatory and Nutritional Index (PINI), and interleukin-6 (IL-6) were measured in blood samples drawn at baseline and at the end of the study. Fecal (1-anti-trypsin and calprotectin were analyzed as markers of intestinal barrier integrity and inflammatory reaction respectively.

Stool quality and fecal microbiological analysis

Fecal samples were collected at baseline and at the last visit 6 weeks after the initiation of the study. Number and consistency of the feces were measured daily during the study period. Bacterial quantification of Lactobacilli and Bifidobacteria was performed.

Statistical analysis

Gut Comfort and Well Being (GCWB) score was the primary outcome and was defined as the mean value of the eight items GCWB questionnaire. A sub-score of the six first items was defined at baseline. Data of all three visits were included in a linear mixed model, ANCOVA with random effect and gender and baseline sub-score as covariates. The model was inquired for treatment difference at final visit and the non-inferiority test was performed, upper 95% confidence limit below 0.5.

The same kind of analysis was performed on stool consistency and stool frequency. *Lactobacilli* and *Bifidobacterium* were log transformed. Treatment effect was adjusted from baseline measurement. According to their distribution, *Lactobacilli* were analyzed through an

ANCOVA and *Bifidobacterium* through a test of Mann-Whitney. Two sided testing were performed.

Reporting of adverse events

All adverse events occurring during the study were reported and recorded no matter what level of severity they had nor whether they were related or not to the nutritional intervention.

RESULTS

Anthropometrics

Participants were between 63 and 101 years old, they were at risk of malnutrition as assessed by the MNA with a score of 20. 4 ± 2.1 (mean ± SD) with a body mass index (BMI) of 25.2 ± 4.9 (mean ± SD).

Compliance and tolerance

For the primary outcome of the study, the score on GCWB after 6 weeks of treatment , no differences were detected between the two groups although the dispersion was quite high. In general the study showed low scores at all the time points tested with a mild trend to increase towards the end. It can be concluded that there is no inferiority between the two groups, thus Clinutren® 1.5 Fibre is tolerated as well as Clinutren® 1.5.

The overall compliance of consumed products was 85% and was similar in both groups. That represents in average 340 ml of products and 510 Kcal/day and corresponds to a daily supplementation of 8.5 g of fiber.

Stool quality and fecal microbiological analysis

There were no differences detected in stool consistency and stool frequency at the end of the study.

The percentage of volunteers that consumed laxatives was higher in the group taking the Clinutren® 1.5 than in the Clinutren® 1.5 Fibre (48.6% v. 32.4%, respectively). When a more detailed analysis was undertaken considering the days with laxatives consumed by the participants in both groups no statistical significance was observed.

The fecal colonization by *Lactobacilli* and *Bifidobacterium* were unexpectedly high in both groups already at baseline. The Group receiving Clinutren® 1.5 Fibre showed a trend to increase colonization by *Lactobacilli* (around 10 times) after the 6 weeks of supplementation (p= 0.08 in ITT and 0.11 in PP). No effect was observed for *Bifidobacterium*.

Biochemical analysis

The PINI normal score in healthy people is < 1. The mean for both groups were within the normal range. However, there is a trend towards higher values in the Clinutren® 1.5 group already at baseline that persisted along the 6 weeks of the study. Similarly CRP values tended to be higher at baseline and persisted so in the same group. No treatment effect was observed. No differences were detected in albumin, pre-albumin and α1-glycoprotein between groups. α1-antitrypsin and calprotectin in feces did not differ between groups neither at baseline nor after 6 weeks supplementation of the diet.

DISCUSSION

This prospective double blind, controlled study was aiming to investigate whether Clinutren® 1.5 Fibre was as well tolerated as Clinutren® 1.5. It was designed like a non-inferiority study using a 8-questions questionnaire on gut comfort and well-being. Each question was graded between 0 (no symptoms) and 4. The volunteers filled the questionnaire four times over 6 weeks supplementation. Most of the evaluations had a very low score without differences between groups, meaning overall that there were no negative effects of either of the supplements and in particular of the fiber supplementation, the main objective of this study.

Since the consumption of the supplement was 85% of the targeted dose the daily dose of fiber (in the Clinutren® 1.5 Fibre group) was around 9 g, 1/3 of which are FOS; another 1/3 acacia gum and around 40% pea outer fiber. The severity of intestinal symptoms due to fiber consumption has been reported in human studies consuming higher quantities, nevertheless the fiber tolerance in elderly individuals may be lower.

This study indicates that the fiber containing supplement won't promote any undesired abdominal symptoms due to fiber in the elderly population.

Moreover, from the 89 enrolled patients only 9 were discontinued due to the appearance of adverse events. No differences, however, were observed in the distribution of abdominal adverse events between groups.

Finally, mild modifications of the intestinal microbiota were observed. Interestingly, despite that the utilized fiber blend is known for the bifidogenic properties, *Lactobacilli* were mildly increased in the fiber supplemented product with only marginal changes for *Bifidobacterium*.

No changes were observed in inflammatory markers. A relevant aspect to take into consideration is that the participants had, despite an MNA score indicating a "risk of malnutrition," a BMI in average higher than 25. In essence, there is possibility that this population of elders were too "healthy" and not suffering from the low noise inflammatory syndrome often observed in ageing people.

EXHIBIT C

Clinutren 1.5

is a range of good tasting, ready to use, high calorie complete milk style drinks.

Nutritional profile

300kcal (1260kJ) per 200ml cup
150kcal (630kJ) per 100ml

- Protein: 15% TEI
  Fat: 30% TEI
  Carbohydrate: 55% TEI
- 5.6g protein per 100ml
- Clinically lactose free, gluten free & residue free

Ingredients

The following is a general ingredient list covering all varieties. For an exact list by variety, refer to the product packaging.

Water, glucose syrup, milk proteins, vegetable oils: corn, rapeseed, soya; sucrose, fat reduced cocoa (chocolate flavour only), potassium chloride, stabiliser: disodium phosphate; emulsifier: mono- and diglycerides of fatty acids; sodium citrate, magnesium chloride, thickener: carrageenan; antioxidant: sodium ascorbate; magnesium oxide, vitamins: C, E, niacin, pantothenic acid, B6, B1 (thiamin), B2 (riboflavin), A, folic acid, K, biotin, D, B12; ferrous sulphate, zinc sulphate, manganese sulphate, copper sulphate, sodium fluoride, sodium molybdate, chromium chloride, potassium iodide, sodium selenite, acidity regulator: potassium hydroxide.
Flavouring and colour according to variety.

Presentation

- Individual 200ml portions, packaged in a plastic cup and sold in a multipack of 4 cups.
- Ready to use.
- Packaged in a protective atmosphere. UHT processed.
- 24 cups of the same flavour (6 multipacks) per carton.

Product range

Vanilla, Chocolate, Apricot, Strawberry/Raspberry, Banana, Coffee.

Uses

Suitable for patients with decreased appetite, malnutrition, or at risk of malnutrition, and with increased energy needs.

Directions for use of product

- Use under medical supervision.
- Suitable as a supplement for patients over 3 years: 1 to 3 units per day.
- Suitable as sole source of nutrition for patients over 6 years: follow medical recommendations.
- Shake before use. Best served chilled.
- Once opened, cover, refrigerate and use within 24 hours.

Nestlé Nutrition

NUTRITIONAL COMPOSITION

			Vanilla / Apricot / Banana / Strawberry-Raspberry per 100 ml	Cafe per 100 ml	Chocolate per 100 ml
ENERGY		kcal	150	150	150
		kJ	630	630	630
PROTEIN	(15%TEI)	g	5.6	5.6	5.6
CARBOHYDRATE	(55% TEI)	g	21	21	21
of which: sugars		g	5.2	4.8	5.3
lactose		g	< 0.25	< 0.25	< 0.25
FAT	(30% TEI)	g	5.0	5.0	5.0
of which: saturates		g	0.70	0.70	0.70
monounsaturates		g	1.9	1.9	1.9
essential fatty acids		g	2.3	2.3	2.2
linoleic acid		g	2.0	2.0	1.9
α-linolenic acid		g	0.30	0.30	0.30
Cholesterol		mg	< 5.0	< 5.0	< 5.0
FIBRE		g	< 0.50	< 0.50	< 0.50
MINERALS					
Sodium		mg	80	80	65
Potassium		mg	170	170	150
Calcium		mg	80	80	80
Phosphorus		mg	80	80	80
Magnesium		mg	30	30	30
Chloride		mg	150	150	75
Iron		mg	1.7	1.7	1.7
Zinc		mg	1.5	1.5	1.5
Copper		mg	0.15	0.15	0.22
Manganese		mg	0.80	0.30	0.34
Fluoride		mg	0.15	0.15	0.15
Chromium		µg	7.5	7.5	10
Molybdenum		µg	11	11	11
Selenium		µg	7.5	7.5	7.5
Iodine		µg	15	15	15
VITAMINS					
Vitamin A		µg RE (IU)	130 (420)	130 (420)	130 (420)
Vitamin D		µg (IU)	1.5 (60)	1.5 (60)	1.5 (60)
Vitamin E		mg α-TE (IU)	2.0 (3.0)	2.0 (3.0)	2.0 (3.0)
Vitamin K		µg	8.3	8.3	8.3
Vitamin C		mg	15	15	15
Thiamin (vit. B1)		mg	0.18	0.18	0.18
Riboflavin (vit. B2)		mg	0.20	0.20	0.20
Pantothenic acid		mg	0.75	0.75	0.75
Vitamin B6		mg	0.26	0.26	0.26
Vitamin B12		µg	0.55	0.55	0.55
Niacin		mg (mg NE)	1.8 (3.0)	1.8 (3.0)	1.8 (3.0)
Folic acid		µg	36	36	36
Biotin		µg	4.5	4.5	4.5
Osmolarity		mosm/l	540-580	580	600
Water content		g	77	77	77

TEI: Total Energy Intake

EXHIBIT D

Clinutren 1.5 Fibre

is a range of good tasting, ready to use, high calorie and fibre enriched milk style drinks specifically formulated to enhance digestive function.

Nutritional profile

300kcal (1260kJ) per 200ml cup
150kcal (630kJ) per 100ml

- Protein: 15% TEI
  Fat: 35% TEI
  Carbohydrate: 50% TEI
- 5.7g protein per 100ml
- 2.6g fibre/100ml

Clinutren 1.5 Fibre contains a unique blend of fructo-oligosaccharides (FOS), acacia, and pea fibre, providing 62 % soluble and 38% insoluble fibre.

Ingredients

The following is a general ingredient list covering all varieties. For an exact list by variety, refer to the product packaging.

Water, glucose syrup, milk proteins, vegetable oils: corn, rapeseed, soya, sucrose, pea fibre, acacia gum, FOS, potassium chloride, emulsifier: mono- and diglycerides of fatty acids, stabiliser: disodium phosphate, sodium citrate, magnesium oxide, antioxidant: sodium ascorbate; thickener: carrageenan; vitamins: C, E, niacin, pantothenic acid, B6, B1 (thiamin), B2 (riboflavin), A, folic acid, K, biotin, D, B12; ferrous sulphate, zinc sulphate, manganese sulphate, copper sulphate, sodium fluoride, sodium molybdate, chromium chloride, potassium iodide, sodium selenite, acidity regulator: potassium hydroxide.
Flavouring and colour according to variety.

Presentation

- Individual 200ml portions, packaged in a plastic cup and sold in a multipack of 4 cups.
- Ready to use.
- Packaged in a protective atmosphere. UHT processed.
- 24 cups of the same flavour (6 multipacks) per carton.

Product range

Vanilla, Plum.

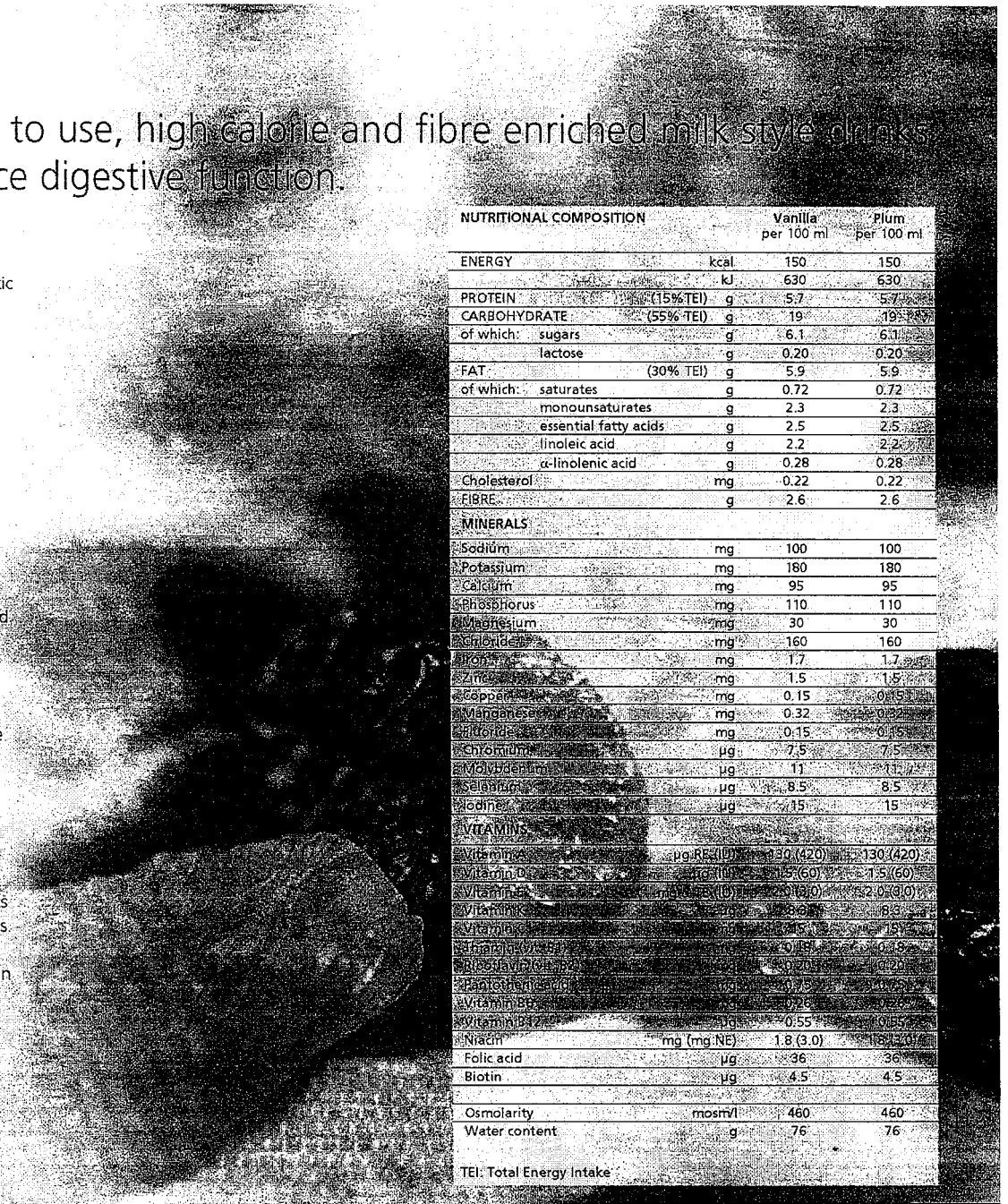
Uses

Suitable for patients with decreased appetite, malnutrition, or at risk of malnutrition, patients with increased energy needs and those who need to improve their digestive and intestinal well-being.
The fibre blend has benefits on stool bulk and intestinal motility, plus a bifidogenic effect to enhance healthy gut microbiota. It helps manage both constipation and diarrhea.

Directions for use of product

- Use under medical supervision.
- Suitable as a supplement for patients over 3 years: 1 to 3 units per day.
- Suitable as sole source of nutrition for patients over 6 years: follow medical recommendations.
- Shake before use. Best served chilled.
- Once opened, cover, refrigerate and use within 24 hours.

Nestlé Nutrition



NUTRITIONAL COMPOSITION			Vanilla per 100 ml	Plum per 100 ml
ENERGY		kcal	150	150
		kJ	630	630
PROTEIN	(15% TEI)	g	5.7	5.7
CARBOHYDRATE	(55% TEI)	g	19	19
of which: sugars		g	6.1	6.1
lactose		g	0.20	0.20
FAT	(30% TEI)	g	5.9	5.9
of which: saturates		g	0.72	0.72
monounsaturates		g	2.3	2.3
essential fatty acids		g	2.5	2.5
linoleic acid		g	2.2	2.2
α-linolenic acid		g	0.28	0.28
Cholesterol		mg	0.22	0.22
FIBRE		g	2.6	2.6
MINERALS				
Sodium		mg	100	100
Potassium		mg	180	180
Calcium		mg	95	95
Phosphorus		mg	110	110
Magnesium		mg	30	30
Chloride		mg	160	160
Iron		mg	1.7	1.7
Zinc		mg	1.5	1.5
Copper		mg	0.15	0.15
Manganese		mg	0.32	0.32
Fluoride		mg	0.15	0.15
Chromium		µg	7.5	7.5
Molybdenum		µg	11	11
Selenium		µg	8.5	8.5
Iodine		µg	15	15
VITAMINS				
Vitamin A		µg RE (IU)	130 (420)	130 (420)
Vitamin D		µg (IU)	1.5 (60)	1.5 (60)
Vitamin E		mg αTE (IU)	2.0 (3.0)	2.0 (3.0)
Vitamin K		µg	8.0	8.0
Vitamin C		mg	45	45
Thiamin (Vit. B1)		mg	0.45	0.45
Riboflavin (Vit. B2)		mg	0.70	0.70
Pantothenic acid		mg	0.75	0.75
Vitamin B6		mg	0.26	0.26
Vitamin B12		µg	0.55	0.55
Niacin		mg (mg NE)	1.8 (3.0)	1.8 (3.0)
Folic acid		µg	36	36
Biotin		µg	4.5	4.5
Osmolarity		mosm/l	460	460
Water content		g	76	76

TEI: Total Energy Intake

EXHIBIT E

NRC Nestlé Research Center

Synergistic Effect of Prebiotics on Human Intestinal Microflora

F. Rochat*, M. Baumgartner, A. Jann, I. Rochat, C. Nielsen, G. Reuteler and O. Ballèvre

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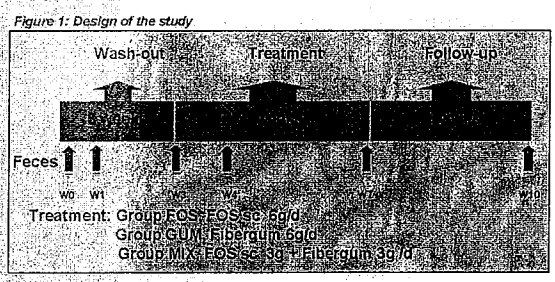
BACKGROUND

To obtain a more pronounced effect on the intestinal microflora with a minimum dose of prebiotics and/or functional carbohydrates, we proposed a synergistic approach. The aim of the study was to demonstrate that a blend of two carbohydrates may stimulate the intestinal growth of bifidobacteria more effectively than each of the same carbohydrates alone.

METHODS

- Randomized, double-blind trial. n = 96 healthy volunteers. 3 groups:
  - FOS: short chain fructo-oligosaccharide (FOS), 6g/d
  - GUM: acacia gum (GUM, Fibergum, CNI, France) , 6g/d
  - MIX: FOS+GUM, 3+3g/d
- Randomization: similar fecal bifidobacteria counts, as well as age and sex distribution among the 3 groups.
- Constrain for volunteers: refrain to eat yoghurt and probiotic products.
- Products: 200ml of skimmed milk with or without tested ingredient. To be taken at the end of the lunch.
- Design: (Fig.1)
  - Control periods (week 0 to 3, and 8 to 10) : control skimmed milk
  - intervention period, 4 weeks (week 4 to 8): skimmed milk FOS and/or GUM.

Figure 1: Design of the study



Variables:

- Part of the intestinal microflora : Bifidobacteria, Lactobacilli, *Enterobacteriaceae, Bacteroides* and *Clostridium perfringens;* semi selective media, confirmation of the lactic acid bacteria by PCR.
- Short Chain Fatty Acids (SCFAs) in feces : GLC-FID analysis.
- Daily record of the abdominal sensation: questionnaire ranking the flatulencies in 5 categories (1: none; 2: light; 3: moderate; 4: socially disturbing; 5: painful).

RESULTS

During the wash-out period a slight decrease of the fecal counts of bifidobacteria was observed, mainly in GUM and MIX groups (Table 1). This is linked to the cessation of probiotic ingestion which is noticeable for some volunteers consuming high amount of dairy products. This effect was less pronounced in subjects of the FOS group.

Changes in fecal bifidobacteria induced by the various treatments were visibly different from one subject to another. The distribution of the observed differences was not symmetric, thus the *t*-test is not appropriate to assess significance.

During the intervention period the major effect on fecal bifidobacteria was observed after one week of treatment in the MIX group (MIX).

Figure 2: Changes in Bifidobacteria during the first week of treatment (Median, Quartiles, Min. & Max., *significant)*

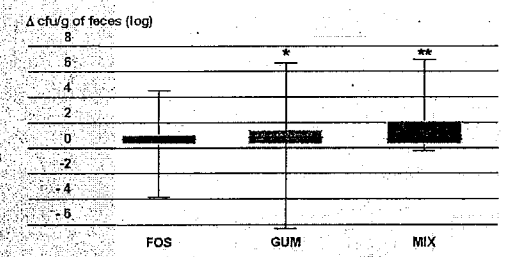
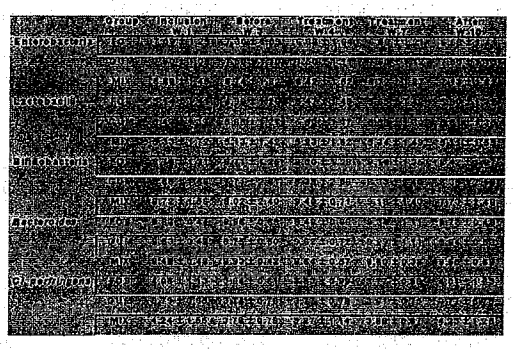


Table 1: Fecal counts of enumerated bacteria (average ±Stdev)



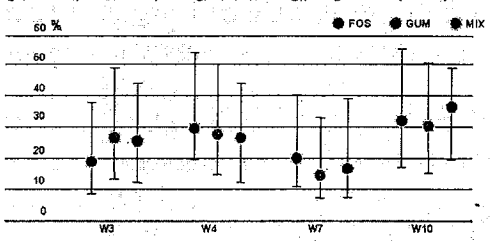
For the GUM group the average increase of +0.67$\log_{10}$ cfu/g is at the limit of statistical significance (95%-CI based on *t* distribution: [-0.11, 1.45]). In the MIX group the average increase is +1.38 $\log_{10}$ cfu/g but the median increase is much lower (+0.4 $\log_{10}$ cfu/g) (Fig. 2).

Thus for the MIX group, a robust M-estimator is used, giving a typical increase of +0.31 $\log_{10}$ cfu/g (95% bootstrap confidence interval: [0.14, 1.00]). We also analyzed the results from a qualitative point of view. 13 out of 29 subjects (44.8%, 95%-CI: [27%, 64%]) had an increase of at least +0.5 $\log_{10}$ cfu/g. With these two methods, we found strong evidence that the change in count of bifidobacteria after one week of treatment with MIX was significant.

No major changes were observed in the other bacterial populations.

The percentage of subjects with *Cl. perfringens* counts above 4 $\log_{10}$ cfu/g decreased slightly at the end of the treatment period, but not significantly.

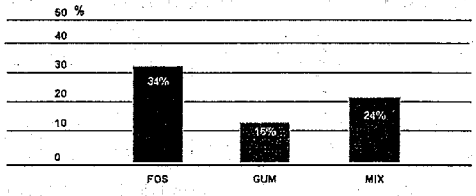
Figure 3: Proportion of C. perfringens above 4 $\log_{10}$ cfu/g of feces (95%-CI)



Variation in SCFA concentrations were not perceptible in fecal samples.

An increase in *moderate* abdominal sensation scores at the beginning of the intervention period was observed, particularly for FOS. For this group, the percentage of *socially disturbing* scores also increased visibly (Fig.4).

Figure 4: Score of moderate abdominal sensation (%) at W3



CONCLUSIONS

A synergy was observed between FOS and GUM on the bifidogenic effect. The effective dose of prebiotic can be optimized in the order to reduce potential abdominal discomfort related to FOS intake. Reliable scientific methods are needed to determine the critical level of perception. A blend of prebiotics may be promising as a real advantage for sensitive populations.